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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,970

08/06/2003

James A. Bianco

1406C

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32516

7590

06/20/2006

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/635,970

Applicant(s)

BIANCO, JAMES A.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Applicant's election with traverse of the species restriction requirement in the reply filed on 5/15/06 is acknowledged. The traversal is on the ground(s) that chemotherapeutic agents tend to be used synonymously in the art. This is not found persuasive because each species has acquired a separate status in the art as evidenced by their different classifications.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (USPN 5,977,163).

The instant invention is drawn to a therapy for the treatment of cancer comprising administering to a patient in need thereof a polymer-taxane conjugate; wherein the the polmer of the polymer –taxane conjugate is poly-1-glutamate and the taxane of said polymer-taxane conjugate is paclitaxel; and one or more of a group comprising chemotherapeutic agents.

Li et al. teaches compositions of paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid, see, i.e., for example, abstract and claims. Li discloses methods could be used to make polymer conjugates of other therapeutic agents, contrast agents, and drugs, including other anti-tumor or anti-cancer drugs. Li teaches such combinations are known in the art and such conjugation would be well within the skill of a routine practitioner of the chemical art, and as such would fall within the scope of the claimed invention, see i.e., for example, column 2, line 61- column 3, line 17.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (USPN 6,262,107).

The instant invention is drawn to a therapy for the treatment of cancer comprising administering to a patient in need thereof a polymer-taxane conjugate; wherein the polymer of the polymer-taxane conjugate is poly-L-glutamate and the taxane of said polymer-taxane conjugate is paclitaxel; and one or more of a group comprising chemotherapeutic agents.

Li et al. teaches compositions of paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid, see, i.e., for example, abstract and claims. Li discloses methods could be used to make polymer conjugates of other therapeutic agents, contrast agents, and drugs, including other anti-tumor or anti-cancer drugs. Li teaches such combinations are known in the art and such conjugation would be well within the skill of a routine practitioner of the chemical art, and as such would fall within the scope of the claimed invention, see i.e., for example, column 2, line 61- column 3, line 17.

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Therefore, the reference is deemed to anticipate the instant claims above.

Conclusion

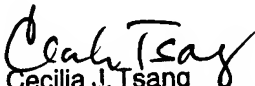
All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Cecilia J. Tsang
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